ISRCTN62029058 https://doi.org/10.1186/ISRCTN62029058

Evaluation of vascular hemodynamics in alveolar bone post exodonty in vivo through experimental endoscopic imagenology: pilot study

Submission date
29/08/2019

Recruitment status
No longer recruiting

Registration date
08/09/2019

Overall study status
Completed

Last Edited
05/09/2019

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Endoscopy has seen significant development over recent years in various medical fields with its application expanding from the support of minimal invasive surgery to in situ imaging. In this context, the application of endoscopic techniques to assess the quality of the regenerated bone in situ in the drill hole before implant placement is an appealing approach. The aim of this study is to use short distance support immersion endoscopy (SD-SIE) to compare the quality of regenerated bone in healed post-extraction sites, which are grafted with an in situ hardening β-TCP, against un-grafted sites, before implant placement. This assessment is based on microscopic bone analysis in combination with the blood vessel count.

Who can participate?
Two groups of patients with ages ranging from 18 to 85, including male and female patients, with native bone (extraction performed without graft material) and regenerated bone (extraction performed with graft material four to six months before the implantation), evaluated at the time of implant cavity preparation

What does the study involve?
Implant sites are assessed using SD-SIE, including blood vessels, mineralised area, non-mineralised area and the amount of resting bone substitute.

What are the possible benefits and risks of participating?
Endoscopic observation allows the detection of possible intraoperative accidents during implant preparation such as bone wall perforation, accidental contact with neurovascular structures and detection of foreign objects. Associated risks during the surgery are the same as with any tooth extraction such as pain and bleeding after the surgery and allergy against the anaesthesia.

Where is the study run from?
Implant Clinic of the Dental School of Universidad de La Frontera, Temuco (Chile)

When is the study starting and how long is it expected to run for?
March 2017 to October 2018

Who is funding the study?
The study was supported with biomaterials from Sunstar Suisse SA, Etoy, Switzerland to the Universidad de La Frontera, Temuco, Chile. Universidad de La Frontera also funded the study via a grant (DIUFRO No. DI17-0170)

Who is the main contact?
Prof. Dr. Víctor Beltrán
victor.beltran@ufrontera.cl

Contact information

Type(s)
Public

Contact name
Dr Victor Beltran

Contact details
Claro Solar 115
Temuco
Chile
4780000
+56 (0)9971258075
victor.beltran@ufrontera.cl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DIUFRO project Nº DI17-0170

Study information

Scientific Title
In situ endoscopic analysis of vascular supply and regenerated alveolar bone in β-TCP grafted and un-grafted post extraction sites before implant placement: a prospective case-control study

Study objectives
The aim of this study was to use short distance support immersion endoscopy (SD-SIE) to compare the quality of regenerated bone in healed post-extraction sites, which are grafted with an in situ hardening β-TCP, against un-grafted sites, before implant placement. This assessment was based on microscopic bone analysis in combination with the blood vessel count.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/03/2017, Universidad de La Frontera Ethics Committee (Postal address: 4780000; Tel: +56 (0)452325775; Email: cec@ufrontera.cl), Decision 118/16

Study design
Pilot prospective case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Dental implant in mandibular or maxillary sites

Interventions
A total of 13 grafted and 13 un-grafted alveolar sites were analyzed with short distance support immersion endoscopy (SD-SIE) in the drill hole right before implant placement. The sites belonged to the anterior maxillary zone including premolars, canines and incisors. All participants' data were anonymized to ensure confidentiality and the grafted and un-grafted groups were randomized for a blind analysis.

Vessels, mineralized and unmineralized zones are measured before implant placement by support immersion endoscopy (SD-SIE) to compare the quality of regenerated bone and healing in post-extraction sites.

The assessment is made based on microscopic bone analysis (SD-SIE) in combination with blood vessel count according to the following protocol: (1) Selection of the area of interest (AoI), (2) Screenshot of images after irrigation and cleaning, (3) Set of the scale bar according to the transversal diameter of the scope window (contact mode) at the center of the image and definition of the area of measurement using Image J software.

Vessels are identified by observing the original video recordings that were recorded by the endoscopic procedure in vivo after cleaning the bone surface with saline solution. The percentages were calculated from area of mm2 by: Unmineralized bone or vessels multiplied by 100 and then divided by the Area of Interest (AoI). The mineralized bone area is calculated from the difference of the AoI from the vessels area selected plus non-mineralized bone. Bright white areas are selected as Bone Substitute. Vessels are counted in a blinded manner. Sites with

pulsatile extravasation from arterial vessels were excluded, if the AoI could not be cleansed sufficiently.

Intervention Type
Other

Primary outcome measure
The implant sites were evaluated using SD-SIE after 4-6 months. SD-SIE was applied in drill holes before implant placement, and videos were taken from representative central buccal areas. Measured at a single timepoint.

Secondary outcome measures
Video recordings analyzed using Image J software for:
1. Number of blood vessels per area (NBV)
2. Relative area of vessels (VA)
3. Relative area of mineralized bone (MBA)
4. Relative area of unmineralized bone (UMBA)
5. Relative area of bone substitute (BSA)
Measured at a single timepoint

Overall study start date
15/03/2017

Completion date
01/10/2018

Eligibility

Key inclusion criteria
1. Patients older than 18 years old
2. Total or partial dentition
3. Indication for a dental implant in adequately formed mandibular or maxillary sites without regenerated bone
4. Indication of a dental implant in mandibular or maxillary sites, previously regenerated

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Minimal 8 patients

Key exclusion criteria
1. Drug abuse
2. Systemic diseases
3. Purulent local inflammation
4. Severe cardiovascular diseases
5. Active orthodontic treatment
6. Heavy smokers (>10 cigarettes/day)

Date of first enrolment
15/05/2017

Date of final enrolment
01/05/2018

Locations

Countries of recruitment
Chile

Study participating centre
The Implant Clinic of the Dental School of Universidad de la Frontera (UFRO)
Claro Solar 115
Temuco
Chile
4780000

Sponsor information

Organisation
Universidad de La Frontera, Temuco, Chile (DIUFRO project Nº DI17-0170)

Sponsor details
Avenida francisco salazar 01145
Temuco
Chile
4780000
+56 (0)45232 5000
cec@ufrontera.cl

Sponsor type
University/education

Website
http://cec.ufro.cl/

ROR
https://ror.org/04v0snf24

Funder(s)

Funder type
Industry

Funder Name
The study was supported with biomaterial from Sunstar Suisse SA, Etoy, Switzerland (DIUFRO-DI17-0170)

Results and Publications

Publication and dissemination plan
BioMed Research International. The special issue: "Biomechanical Properties of Biomaterials /Scaffolds for Bone Tissue Regeneration"

Intention to publish date
01/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Dr Víctor Beltrán (victor.beltran@ufrontera.cl), Prof. Dr Wilfried Engelke (wengelke@med.uni-goettingen.de) and Dr Márcio Lazzarini (lazzarini@em.mpg.de).

IPD sharing plan summary
Available on request